DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2015

Omron Healthcare, Inc.
% Paul Dryden
Consultant
ProMedic, Inc.
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K141978
Trade/Device Name: Maxpower relief (PM3032)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 19, 2014
Received: October 21, 2014

Dear Mr. Dryden,

This letter corrects our substantially equivalent letter of December 3, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S
Carlos L. Peña, PhD, MS
Division Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name

Maxpower relief (PM3032)

Indications for Use *(Describe)*

This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulder or foot due to strain from exercise or normal household and work activities.

Environments of Use: Clinics, hospital and home environments

Patient Population: Adult

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Official Contact: Renee Thornborough – Director QA/RA

Proprietary or Trade Name: PM3032

Common/Usual Name: Transcutaneous electrical nerve stimulator for pain relief.

Classification Name/Code: NUH – stimulator, nerve, transcutaneous, over-the-counter
21CFR 882.5890
Class II

Device Name: Maxpower relief

Predicate Devices: K110068 – Omron – PM3030
K121757 – Healthmate International – Pro8AB

Device Description:
The Maxpower relief (Model PM3032) is a small, battery operated TENS device for pain relief intended for OTC use. The device complies with AAMI ANSI ES60601-1, IEC 60601-1-2 and IEC 60601-2-10.

The output modes are intended for application to the following areas: lower back, arms, legs, shoulder or foot. The specifications of each mode will be discussed in greater detail later in this section.

Software controls all controls and indicators. Software controls waveform characteristics.

This device is intended for the relief of pain associated with sore or aching, muscles of the shoulder, lower back, arms, or legs due to strain from exercise or normal household and work activities.

The accessories include an electrode cord / cable and electrodes pads (Long Life) which are placed on the specific body part.

As above the device is battery powered there is no connection to AC mains supply nor connection to any other device.

We have provided the information suggested in *Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use* from April 5, 2010. A checklist in accordance with this guidance can be found in Section 18 of this submission

Intended User
OTC

Patient Population
Adults

Indications for Use:
This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulder or foot due to strain from exercise or normal household and work activities.

Environment of Use:
Clinics, hospital and home environments

Contraindications:

- Use with a pacemaker or other implanted metallic or electronic device.
- Use with a life-supporting medical electronic device such as an artificial heart or lung or respirator
- Use in the presence of monitoring equipment (e.g. cardiac monitors, ECG alarms)
- Simultaneous connection of a patient to a high frequency surgical unit
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment
- Use with another TENS device

Predicate Device Comparison:
The Maxpower relief (PM3032) was compared to the predicates PM3030- K110068 and Healthmate Pro-8B – K121757 in the device comparison Table 5.1 below. Detailed electrical characteristics are provided in **Table 5.2**.

Table 5.1 Device Comparison

Model Name 510(k) Number	New Device Maxpower relief (PM3032)	Predicate Device PM3030 K110068	Predicate Device Pro-8AB K121757	Comment
Manufacturer	OMRON HEALTHCARE	OMRON HEALTHCARE	Healthmate International	-
Indications for use	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulder or foot due to strain from exercise or normal household and work activities.	This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	To be used for temporary relief of pain with sore and aching muscles in the shoulder, waist, back, neck upper extremities(arm), and lower extremities(leg), due to strain from exercise or normal household work activities.	Substantially equivalent
Prescriptive	No, OTC	No, OTC	No, OTC	Identical
Power Source(s)	two AAA alkaline batteries	two AAA alkaline batteries	Rechargeable battery	PM3030 and PM3032 identical
- Method of Line Current Isolation	N.A. not line powered	N.A. not line powered	N.A. not line powered	Identical all battery powered
Patient Leakage Current - Normal Condition (uA)	1	<0.1	Not specified	All three device comply with 60601-1 leakage current requirements
Patient Leakage Current - Single Fault Condition (uA)	8.9 max with mains (250vAC/60Hz)	N.A	Not specified	All three device comply with 60601-1 leakage current requirements

Model Name 510(k) Number		New Device Maxpower relief (PM3032)	Predicate Device PM3030 K110068	Predicate Device Pro-8AB K121757	Comment
Average DC current through electrodes when device is on but no pulse are being applied (uA)		0 (uA)	0 (uA)	0 (uA)	Identical
Number of output Modes		9	3	8	-
Number of output channels	Synchronous or Alternating	1 ch	1 ch	2 ch	PM3030 and PM3032 identical
	Method of Channel Isolation	None, single channel	None, single channel	Not specified	PM3030 and PM3032 identical
Regulated Current or Regulated Voltage		Regulated Current	Regulated Current	Not specified	PM3030 and PM3032 identical
Software/Firmware/Microprocessor Control		Microprocessor	Microprocessor	Not specified	PM3030 and PM3032 identical
Automatic Overload Trip		No	No	Not specified	PM3030 and PM3032 identical
Automatic No-Load Trip		Yes	No	No	PM3032 contains circuit which will stop stimulation if pads are not properly adhered
Automatic shut Off		Yes	Yes	Yes	Identical
User over ride control		User activated On/Off	User activated On/Off	User activated On/Off	Identical

Model Name 510(k) Number		New Device Maxpower relief (PM3032)	Predicate Device PM3030 K110068	Predicate Device Pro-8AB K121757	Comment
Indication display	ON/Off status	Yes	Yes	Yes	Identical
	Low Battery	Yes	No	Yes	PM3032 and Pro-8AB identical
	Voltage/Current Level	Yes	Yes	Yes	Identical
Timer Range (minutes)		15	15	10-60	
Compliance with Voluntary standards		ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	PM3032 complies with currently recognized version of 60601-1
Compliance with 21 CFR 898		Yes (by compliance with 8.5.2.3 of ES 60601-1)	Yes	Not specified	PM3032 and PM3030 identical
Weight		Approx. 100g (incl. batteries)	Approx. 60g (incl. batteries)	Approx. 54g (incl. batteries)	Similar
Dimensions (W x H x D)		52(W)x112(H)x25(D)mm	55(W)x95(H)x18(D)	50(W)x93(H)x10(D)	Similar
Patient contact		Long Life Pads	Long Life Pads	Not specified	Identical electrode pads. The Long Life Pads (K120516)

Table 5.2 Detailed Electrical Comparisons Output Specifications Maxpower relief (PM3032) Compared to Predicate Pro-8AB K121757

Parameter		Maxpower relief (PM3032)									Predicate Pro-8AB K121757							
Mode of Program Name		TAP	KNEAD	RUB	ARM	LBACK	LEG	FOOT	JOINT	SHLDR	M1	M2	M3	M4	M5	M6	M7	M8
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	66.3	51.1	42.3	66.3	66.3	66.3	66.3	66.3	66.3	43.9	54.0	85.8	41.9	42.0	83.9	44.0	85.9
	@2kΩ	87.6	67.9	55.9	87.9	87.9	87.9	87.9	87.9	87.9	81.9	102.0	145.9	77.8	79.9	145.6	83.9	145.4
	@10kΩ	95.9	73.9	59.9	95.9	95.9	95.9	95.9	95.9	95.9	146.4	159.9	159.8	137.0	141.7	158.1	147.8	159.9
Maximum Output Current [mA]	@500Ω	132.6	102.2	84.6	132.6	132.6	132.6	132.6	132.6	132.6	87.8	108.0	171.6	83.8	84.0	167.8	88.0	171.8
	@2kΩ	43.8	34.0	28.0	44.0	44.0	44.0	44.0	44.0	44.0	41	51.0	73.0	38.9	40.0	72.8	42.0	72.7
	@10kΩ	9.6	7.4	6.0	9.6	9.6	9.6	9.6	9.6	9.6	14.6	16.0	16.0	13.7	14.2	15.8	14.8	16.0
Duration of primary phase [usec]		100	150	150	100	150	100	100	100	100	90	90	90	90	90	90	90	90
Pulse Duration [usec]		100	150	150	100	150	100	100	100	100	90	90	90	90	90	90	90	90
Frequency [Hz]		1 - 15.43	25.28-79.22	84.86-132	1 - 132	1 - 237.6	1 - 19.16	1 - 19.16	42.43-237.6	1 - 19.16	59	12 - 47	1.7	95	94	1.7 - 59	59	1.7 - 94
For multiphasic waveforms only:	Symmetrical phases	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Phase Duration	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Net Charge(μC per pulse) (@500Ω) [uC] *		0	0	0	0	0	0	0	0	0	0	0	1	2	3	4	5	6
Maximum Phase Charge (@500Ω) [uC]		13.26	15.33	12.69	13.26	19.89	13.26	13.26	13.26	13.26	7.9	9.72	15.44	7.54	7.56	15.10	7.92	15.46
Maximum Current Density (@500Ω) [mA/cm^2]		3.03	2.33	1.93	3.03	3.03	3.03	3.03	3.03	3.03	3.38	4.16	6.62	3.23	3.24	6.47	3.39	6.62
Maximum Average Current (@500Ω) [mA]		0.17	0.37	0.71	0.83	0.38	0.43	0.17	0.22	0.88	0.47	0.46	0.03	0.72	0.71	0.89	0.47	1.45
Maximum Average Power Density (@500Ω) [W/cm^2]		0.00017	0.00020	0.00039	0.00060	0.00015	0.00040	0.00016	0.00015	0.00082	0.00079	0.00095	0.00009	0.00116	0.00115	0.00288	0.00079	0.00481
Burst Mode	(a) Pulses per burst	46	71	118	23	1425	57	57	1425	76	159	940	N/A***	66	1786	940	295	1767
	(b) Bursts per sec	0.33	0.59	0.59	1.00	0.14	0.25	0.25	0.14	0.20	0.24	0.05	N/A***	0.87	0.04	0.05	0.15	0.05
	**(c) Burst duration	3	8.5	17	8	14	8	8	14	10	4.2	21.1	N/A***	1.15	23	21.17	6.6	20.5
	(d) Duty cycle: Line(b)xLine(c)	1	5	10	8	2	2	2	2	2	1	1	N/A***	1	1	1	1	1
ON Time (seconds)		3	0.9	0.9	0.3	6	3	3	6	4	2.7	20	N/A***	0.7	19	20	5	18.8
OFF Time (seconds)		0	0.8	0.8	0.7	1	1	1	1	1	1.5	1.1	N/A***	0.45	4	1.17	1.6	1.7
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Output Specifications Maxpower relief (PM3032) Compared to Predicate PM3030 K110068

Parameter		Maxpower relief (PM3032)									Predicate PM3030 K110068		
Mode of Program Name		TAP	KNEAD	RUB	ARM	LBACK	LEG	FOOT	JOINT	SHLDR	Arm Mode	Lower Back Mode	Leg/foot Mode
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	66.3	51.1	42.3	66.3	66.3	66.3	66.3	66.3	66.3	34.4	33.0	34.2
	@2kΩ	87.6	67.9	55.9	87.9	87.9	87.9	87.9	87.9	87.9	46.0	43.2	45.2
	@10kΩ	95.9	73.9	59.9	95.9	95.9	95.9	95.9	95.9	95.9	49.6	48.0	50.4
Maximum Output Current [mA]	@500Ω	132.6	102.2	84.6	132.6	132.6	132.6	132.6	132.6	132.6	68.8	66.0	68.4
	@2kΩ	43.8	34.0	28.0	44.0	44.0	44.0	44.0	44.0	44.0	23.0	21.6	22.6
	@10kΩ	9.6	7.4	6.0	9.6	9.6	9.6	9.6	9.6	9.6	5.0	4.8	5.0
Duration of primary phase [usec]		100	150	150	100	150	100	100	100	100	100	100	100
Pulse Duration [usec]		100	150	150	100	150	100	100	100	100	100	100	100
Frequency [Hz]		1 - 15.43	25.28-79.22	84.86-132	1 - 132	1 - 237.6	1 - 19.16	1 - 19.16	42.43- 237.6	1 - 19.16	2 - 51.65	2 - 108	2 - 11
For multiphasic waveforms only	Symmetrical phases	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Phase Duration	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Net Charge(μC per pulse) (@500Ω) [uC] *		0	0	0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (@500Ω) [uC]		13.26	15.33	12.69	13.26	19.89	13.26	13.26	13.26	13.26	6.88	6.60	6.84
Maximum Current Density (@500Ω) [mA/cm²]		3.03	2.33	1.93	3.03	3.03	3.03	3.03	3.03	3.03	1.57	1.51	1.56
Maximum Average Current (@500Ω) [mA]		0.17	0.37	0.71	0.83	0.38	0.43	0.17	0.22	0.88	0.29	0.58	0.07
Maximum Average Power Density (@500Ω) [W/cm²]		0.00017	0.00020	0.00039	0.00060	0.00015	0.00040	0.00016	0.00015	0.00082	0.00018	0.00035	0.00005
Burst Mode	(a) Pulses per burst	46	71	118	23	1425	57	57	1425	76	180	540	33
	(b) Bursts per second	0.33	0.59	0.59	1.00	0.14	0.25	0.25	0.14	0.20	0.11	0.10	0.17
	**(c) Burst duration	3	8.5	17	8	14	8	8	14	10	18	20	6
	(d) Duty cycle: Line(b)xLine(c)	1	5	10	8	2	2	2	2	2	2	2	1
ON Time (seconds)		3	0.9	0.9	0.3	6	3	3	6	4	8	10	6
OFF Time (seconds)		0	0.8	0.8	0.7	1	1	1	1	1	1	0	0
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

(*): Because The energy will be discharged to GND after an output of pulse
(**): Burst duration = pulse train duration
(***): Endurande model Automode I doesn't have a burst mode.

Differences Between Other Legally Marketed Predicate Devices:
The Omron Maxpower relief (PM3032) is viewed as substantially equivalent to the predicate devices because: The Maxpower relief (PM3032) uses the exact same technology and has substantially equivalent indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulder or foot due to strain from exercise or normal household and work activities. These indications are virtually identical to the predicates.

Prescriptive – The Maxpower relief (PM3032) and predicates are all OTC.

Design and Technology – The Maxpower relief (PM3032) has equivalent design and features when compared to the predicates and has the identical technology to the predicate PM3030.

Performance and Specifications – The Maxpower relief (PM3032) has equivalent specifications of performance when compared to the predicates.

Compliance with standards – The predicate devices declare compliance with IEC 60601-1 and IEC 60601-1-2. The PM3032 complies with AAMI ANSI ES6060-1 (which replaced IEC 60601-1) and IEC 60601-1-2. The Pro-8AB and PM3032 comply with IEC 60601-2-10. Additionally the PM3032 complies with IEC 60601-1-11 for home healthcare.

Materials –
The patient contacting materials of the Maxpower relief (PM3032) are the Long Life Pads. The Long Life Pads and were tested and the data presented in K120516.

- Irritation and delayed-type hypersensitivity Extract in accordance with ISO 10993-10
- Closed-patch test for delayed hypersensitivity Rabbits in accordance with ISO 10993-10
- Cytotoxicity in accordance with ISO 10993-5

Patient Population –
The Maxpower relief (PM3032) and predicates are indicated for adults

Environment of Use – Clinics, hospital and home environments. Identical to the predicate K110068

Non-Clinical Testing Summary:

The device has been tested to insure that all requirements have been met, this includes:

- Testing of all controls

- Testing of all indicators
- Testing of battery state indicators
- Testing of waveforms

The device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance

- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests

- IEC 60601-1-11: 2010, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- IEC 60601-2-10: 2012 Medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators

The device has also been tested for drop, vibration and environmental temperature and humidity

Usability testing has also been performed.

Clinical Testing Summary:
No clinical testing was performed

Substantial Equivalence Conclusion
Omron maintains that the Maxpower relief (PM3032)is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.